# QUALITY ASSURANCE MANUAL

UNCONTROLLED COPY MARCH 1997

# QUALITY POLICY

**We will respond to the needs and expectations of our customers by:**

- **delivering products and services which are free from defects;**
- **complying in every respect with the requirements of appropriate regulatory authorities; and**
- **complying with the ISO 9001 quality standard.**

# CERTIFICATION

We, the undersigned, certify that this Quality Assurance Manual states the policies and responsibilities for quality and describes the functional procedures and the system currently being used by Theratronics International Limited.

The Quality Assurance program provides procedures which meet the requirements of ISO 9001, CAN3-Z299.2-1985, Z299.3-1985, Z299.4-1985, USFDA GMP, Health Canada, European Medical Device Directive 93/42/EEC and EN 46001.

The Management fully endorses the Quality Assurance program as detailed in this manual.

E.S. Martell
Vice-President
Quality Assurance & Regulatory Affairs

Date

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# 1. INTRODUCTION

## 1.1 SCOPE

This manual describes the Quality Assurance Program of Theratronics International Limited, 413 March Road, Kanata, Ontario, Canada for the design, manufacture, distribution and servicing of radiation therapy devices, computer equipment, and miscellaneous contract manufacturing products.

The Software Quality Assurance Program of Theratronics International Limited is defined in the Software Quality Assurance Manual, 5.07-AA-00.

## 1.2 REGULATORY AND QUALITY SYSTEM COMPLIANCE

The Theratronics Quality Assurance Program is compliant with ISO 9001, EN 46001, the U.S. Federal Food and Drug Administration GMP Program, Health Canada Medical Device Regulations, European Medical Device Directive 93/42/EEC and Canadian Standards Association Quality Standard CAN 3-Z299.2

Theratronics has successfully implemented a quality system which has been registered as compliant with ISO 9001. The scope of registration is **"Design, manufacture, distribute and service radiation therapy equipment hardware and software for the treatment of cancer, and manufacture specialty products under contract."**

Theratronics Quality Assurance Program has been assessed and registered as meeting the requirements of the European Medical Device Directive 93/42/EEC, annex II. The applicability of each element of the Directive 93/42 EEC is detailed in a checklist which is included in the Technical File Summary for each CE marked model.

The applicability of each element of EN 46001 is detailed in a checklist issued as specification DG1467 G97/G98.

## 1.3 QUALITY POLICY

The THERATRONICS Quality Policy is understood, implemented and maintained by all personnel of the organization.

# 2. RESOURCES

THERATRONICS shall provide adequate resources, including the assignment of trained personnel, for management, performance of work and verification activities including internal quality audits.

## 3. MANAGEMENT REPRESENTATIVE

The management representative is responsible for ensuring that the requirements of this manual are implemented and maintained is the Vice-President, Quality Assurance & Regulatory Affairs.

The Vice-President, Quality Assurance & Regulatory Affairs, is responsible for the contents of the THERATRONICS Quality Assurance Manual and Quality Assurance Procedures Manual and is given full authority of the President & Chief Executive Officer to deal with all Quality issues to satisfy THERATRONICS' customers and regulatory authorities.

It is the responsibility of the Vice-President, Quality Assurance & Regulatory Affairs to report to Senior Management on the performance of the quality system and to include any recommendations for improvement.

Any problems, differences or non conformities which cannot be resolved within the organizational structure may be referred directly to the President & Chief Executive Officer of THERATRONICS for resolution.

## 4. MANAGEMENT REVIEW

A review package shall be prepared by Quality Assurance on a quarterly basis which includes reports summarizing internal audits, complaints, major item nonconformances, corrective actions and preventive actions. Senior Management shall review this documentation to assure the continued adequacy and effectiveness of the Quality System, and to assure that product quality concerns are appropriately addressed. Minutes of the review including any comments or recommendations will be recorded and filed by Quality Assurance. Any actions required will be assigned and tracked by the Vice-President of Quality Assurance & Regulatory Affairs.

## 5. QUALITY ASSURANCE DOCUMENTATION

The Quality Assurance Manual describes the Company Quality Assurance Program. The manual defines the administration and control of the manual, and the responsibilities and authorities of personnel within the organization.

The Quality Assurance Procedures Manual describes the responsibility, procedures and forms required to comply with applicable Quality Standards.

Certain Quality Assurance Procedures (QAP's) are supplemented by Standard Operating Procedures (SOP's) which are issued and maintained by the originating departments. If there is conflict, the Quality Assurance Procedure shall take precedence over the supporting SOP.

Requests for revisions to any part of the Quality Assurance Manual or Quality Assurance Procedures Manual may be directed in writing, to the Vice-President, Quality Assurance

& Regulatory Affairs at any time. A justification for the request should be included. All such requests will be evaluated at the time of the applicable document's review and all approved requests will be incorporated.

In accordance with the European Medical Device Directive, SGS Yarsley must be informed of substantial changes to the quality system. SGS Yarsley is the European notified body retained by THERATRONICS for CE Mark purposes.

## 6. MANUAL CONTROL

### 6.1 QUALITY ASSURANCE MANUAL

The Quality Assurance Manual shall be issued to executive staff who are responsible for managing, performing and verifying work affecting quality and to customers on request.

Copies of Quality Assurance manuals shall be returned to Quality Assurance upon request or when leaving the company.

### 6.2 QUALITY ASSURANCE PROCEDURES MANUAL

The Quality Assurance Procedures Manual shall be issued to all executive, managerial and supervisory staff responsible for and engaged in, Marketing, Sales, Service, Technical Support, Engineering, Manufacturing, Production Control, Materials Control, Quality Assurance, Quality Control functions.

Each manual copy shall be serialized and Quality Assurance shall maintain a distribution list and revision records.

Each holder of the manual shall be responsible for the condition and updating of their copy of the manual upon receipt of amendments and for returning a completed acknowledgment form to Quality Assurance. The Holder is also responsible for ensuring that employees have read and understood the current issue, where required for the performance of their work.

Amendments shall be issued to each manual holder by Quality Assurance by means of an official document transmittal form. Quality Assurance shall maintain adequate records of all acknowledgment forms received from each manual holder.

## 7. QUALITY ASSURANCE STANDARDS

Explanation of Quality Assurance Standard Designations contained in the Quality Assurance Manual is as follows:

Reference to CSA, shall be interpreted as meaning CAN3-Z299.2-85, CAN3-Z299.3-85 and CAN3-Z299.4-85 Quality Assurance Standards.

Reference to GMP, shall be interpreted as meaning USFDA 21CFR Part 820 Good Manufacturing Practices and Health Canada Medical Device Regulations.

# 8. MANAGEMENT POLICIES & OBJECTIVES OF MAJOR FUNCTIONAL GROUPS

## 8.1 MANUFACTURING

The objective and policy of Manufacturing is to manufacture, assemble, test, pack and ship, products and components in accordance with company quality assurance requirements and product specifications and to satisfy all contractual and regulatory requirements.

Manufacturing is responsible for maintenance of the plant facilities and the planning and control of manufacturing processes in accordance with the requirements of customers, Engineering and Development Groups and regulatory authorities.

Manufacturing is responsible for controlling the purchasing, receiving, handling, storage and issuance of raw materials and other purchased items. This control is to ensure that: the correct items are purchased, protected from damage and deterioration and identification and traceability requirements are met.

Manufacturing is responsible for controlling manufactured parts, components and assemblies in such a manner that they are protected from damage and deterioration, and that the identification is preserved to ensure conformity to design detail.

## 8.2 QUALITY ASSURANCE & REGULATORY AFFAIRS

It is the objective and policy of Quality Assurance to maintain an effective and efficient Quality Assurance Program by establishing and implementing quality policies and procedures. Such policies and procedures are prepared with the cooperation and assistance of the department managers and in accordance with Quality Assurance Standards and Regulations.

Quality Assurance is responsible for preparing plans for the control of quality in advance of work so that evidence of conformity with contract requirements is obtained.

Quality Assurance is responsible for providing continuing evidence of compliance with the policies and procedures in this manual through internal audits and retention of quality records.

Quality Assurance is responsible for providing comprehensive training in the quality policy and objectives as described in the Quality Manual. This Quality training is provided to THERATRONICS personnel, as appropriate, and will cover the specific needs of each department.

Quality Assurance is responsible for maintaining a system of review and revision of the procedures within this manual such that control of compliance with contractual requirements is assured.

Quality Assurance is responsible for directing the investigation, analysis, reporting and resolution of all complaints received by the company.

Regulatory Affairs is responsible for ensuring that the company conforms to and obtains the necessary approvals from those regulatory authorities having control over the products manufactured, shipped and installed.

## 8.3 ENGINEERING & DEVELOPMENT

The objective and policy of Engineering & Development is to design and develop new products for all Company product lines. Engineering & Development offer technical product support and are responsible for changes to existing products within the Company product lines.

## 8.4 MARKETING

The objective and policy of the Marketing Department is to direct the marketing activities worldwide for all THERATRONICS products while improving marketing efforts for all THERATRONICS products.

## 8.5 SALES

The objective and policy of the Sales Department is to disseminate information and to provide knowledgeable advice on the full range of THERATRONICS' products to Customers and agents throughout the world and to ensure that the Customers needs and expectations will be fulfilled in the sales orders that may result.

It is also the objective and policy of Sales to ensure that all aspects of customer orders are in compliance with Company policies and procedures including but not limited to contract terms and conditions and approval of Letters of Credit. In addition, National and International laws including compliance with Radioactive Material Transport Regulations and Radioactive Materials licensing requirements shall be complied with for all shipments of Radioactive materials.

## 8.6 SERVICE

The objective and policy of the Service, Installation and Technical Support Department is to provide parts, cobalt replacement sources, maintenance and servicing support in a professional, helpful and competent manner to all THERATRONICS customers and agents throughout the world. This Department establishes and maintains procedures (ref. SOP 4.01 and 4.02 series) for performing and verifying that servicing meets all requirements specified in the contract.

The objective and policy of the departments performing installation is to ensure that all of the Company's products are installed and commissioned such that they meet Company Quality Assurance and Product specifications. It is also their objective and policy to

ensure that the equipment is clearly explained and demonstrated to the customer. Installation is the responsibility of the Manager, Installation and Service.

## 9. ORGANIZATION, RESPONSIBILITIES AND AUTHORITIES

### 9.1 ORGANIZATIONS COVERED BY THE QUALITY ASSURANCE PROGRAM

The design, development, manufacture, inspection and test, installation, service, sale and distribution activities subject to the requirements of this Quality Assurance Manual are performed under the executive direction of the President & Chief Executive Officer, THERATRONICS.

The President & Chief Executive Officer has reporting to him, the following functional organizations responsible for implementing the Quality Assurance Program:

a) Manufacturing

b) Quality Assurance & Regulatory Affairs

c) Engineering & Development

d) Finance & Administration

e) Human Resources

f) Marketing

g) Sales

h) Service

Any changes made to the organization before revision of this document are reflected in the organization charts in the "THERATRONICS Organization List', issued on a regular basis by Human Resources.

All management are responsible for assuring that the quality policies as defined in the Quality Manual and applicable quality procedures are understood, implemented and maintained by all personnel in their organization. This shall be accomplished by providing Quality System training for all appropriate personnel.

### 9.2 PRESIDENT & CHIEF EXECUTIVE OFFICER

The President & Chief Executive Officer of THERATRONICS has overall responsibility and authority for the corporate Quality Assurance Program and for ensuring that all operations are carried out in compliance with the Quality Assurance Policies, Procedures, Standards and Guidelines.

### 9.3 VICE-PRESIDENT, MANUFACTURING

The Vice-President, Manufacturing is responsible for production engineering, process planning, scheduling, production control, purchasing, manufacturing, testing, storage,

handling and packing of all products and components manufactured by THERATRONICS. The Vice-President, Manufacturing is also responsible for worldwide service having the authority to establish duties and responsibilities and to authorize working procedures and guidelines within these Departments.

## 9.4 VICE-PRESIDENT, QUALITY ASSURANCE & REGULATORY AFFAIRS

The Vice-President Quality Assurance & Regulatory Affairs is responsible for the development and administration of the Company's quality and regulatory affairs systems. This includes:

a) maintaining the Quality Manual and introducing changes to meet changing internal needs and new regulatory requirements;

b) monitoring quality system compliance through internal audits or direct administration;

c) identifying required corrective actions and ensuring that they are accomplished;

d) interacting with regulatory authorities to demonstrate compliance with requirements;

e) anticipating the company's future needs regarding quality systems and planning to meet them; and

f) managing inspection and testing.

## 9.5 VICE-PRESIDENT, ENGINEERING & DEVELOPMENT

The Vice-President, Engineering & Development is responsible for design, development and technical product support of the products handled by the department. The Vice-President, Engineering & Development has the authority to establish duties and responsibilities and to authorize working procedures and guidelines within this department.

In addition, the Vice-President, Engineering & Development has responsibility for:

a) training and development of Engineering & Development personnel and directing their activities in accordance with established policies, procedures and guidelines.

b) defining the responsibilities and authority of personnel responsible for product design and support, marketing and technical support.

c) specifying, by means of Functional Product Specifications, Engineering Specifications, Engineering Drawings and Sales Specifications, all necessary design, safety, performance and quality requirements for both new and existing Products.

d) monitoring the product to ensure that all required design, safety, regulatory and quality requirements as specified in Product Specifications, are being met.

e) monitoring Customer satisfaction with the Department's products.

## 9.6 VICE-PRESIDENT, FINANCE & ADMINISTRATION

The Vice-President, Finance & Administration is responsible for the financial affairs of the Corporation which includes the responsibility for financial reporting and internal financial control, safekeeping of assets, banking and treasury functions, taxation and payroll for the company, administration services, risk management and Business Systems. The Vice-President, Finance & Administration has the authority to establish duties and responsibilities and to authorize working procedures and guidelines pertaining to the above for the Corporation.

## 9.7 VICE-PRESIDENT, SALES & MARKETING

The Vice-President, Sales & Marketing is responsible for the worldwide marketing activities for all THERATRONICS products and improving marketing efforts for all products. The Vice-President Sales & Marketing is also responsible for product sales worldwide, providing knowledgeable advice on the full range of THERATRONICS products to Customers and agents.

## 9.8 DIRECTOR, HUMAN RESOURCES

The Director, Human Resources is responsible for the operation of the Human Resources group which includes the responsibility for employee/labour relations, staffing, compensation and employee and environmental health and safety. The Director, Human Resources has the authority to establish duties and responsibilities and to authorize working procedures and guidelines within this group.

## 9.9 DIRECTOR, SALES

The Director of Sales reporting to the Vice-President, Sales & Marketing is responsible for product sales worldwide, providing knowledgeable advice on the full range of THERATRONICS' products to Customers and agents.

## 9.10 PLANT AND PROCESS ENGINEER

The Plant and Process Engineer is responsible for maintenance of the plant facilities and for the following production engineering functions:

a) preparing or having prepared workmanship standards and manufacturing procedures for special processes and providing training to manufacturing and Production Planning Staff.

b) producing estimates and/or submitting quotations for manufacturing including contract work calling for CSA Quality Assurance Program requirements.

c) administering the contract manufacturing program to ensure that all contractual commitments to customers are met.

d) ensuring that all data provided by customers and/or regulatory agencies has been incorporated into Process Sheets and related documents prior to release for manufacture.

e) approving Process Sheets and related documents prior to release for manufacture when required by contract.

## 9.11 PLANT MANAGER

The Plant Manager is responsible for:

a) training and development of all Shop personnel and directing their activities in accordance with established policies, procedures and guidelines.

b) assigning Manufacturing Orders, drawings, specifications, procedures, materials, components, tooling and N/C tapes to the specified work centre. If necessary, selects alternate work centre in co-operation with Production Planning staff, in order to maintain schedules.

c) ensuring that work centres are maintained in a safe and fully operational condition.

d) ensuring that work centre operators are qualified to perform the work as specified on the Manufacturing Order.

e) ensuring that Manufacturing Order and quality related instructions are followed throughout the manufacturing process.

f) issuing policies, procedures and guidelines for the safe and proper storage and handling of materials, components, tooling and fixtures and ensuring that these are followed to protect items from loss, damage or deterioration.

g) ensuring that all special handling and storage instructions as specified on Inventory Data Sheets or Manufacturing Orders are implemented and followed by Stores and Shop personnel.

h) ensuring the physical security of the Stores is maintained at all times including authorization for entry or restricting entry as appropriate.

## 9.12 MANAGER, MATERIALS CONTROL

The Manager, Materials Control is responsible for:

a) training and development of Materials Control personnel and directing their activities in accordance with established policies and procedures.

b) issuing policies, procedures and guidelines for the Materials Control operation.

c) maintaining and distributing the manufacturing control procedures manual.

d) scheduling of purchased material requirements in co-operation with Production Planning.

e) procuring equipment, materials, supplies and services in accordance with inventory data sheets and correct revisions of drawings, specifications and procedures.

f) ensuring that only suppliers on the Quality Assurance Approved Vendors List are used for the procurement of products and services where required under CSA Quality Program requirements.

g) ensuring that, where necessary, any errors and omissions on the part of the supplier are corrected promptly, and that adequate records are maintained to confirm corrective action taken.

h) maintaining and reviewing records of defective purchased items and taking corrective action to prevent recurrence.

i) preparing and issuing manufacturing order packages including the correct revision of drawings, specifications and procedures.

## 9.13 MANAGER, PRODUCTION PLANNING AND CONTROL

The Manager Production Planning and Control is responsible for:

a) training and development of Production Planning and Control personnel and directing their activities in accordance with established policies, procedures and guidelines.

b) issuing policies, procedures and guidelines for the Production Planning and Control operations.

c) issuing Production Schedules based on the Master Production Plan and customer requirements. Allocates production units to specific Customer orders.

d) coordinating planning, purchasing and manufacturing activities in order to meet production schedules.

e) assigning the preparation of Process Sheets and related documents to Production Planning staff.

f) ensuring that all data provided by customers, Engineering and Development Groups, and/or regulatory agencies has been incorporated into the Process Sheets and related documents prior to release for manufacture.

g) preparing Process Sheets, Inventory Data Sheets and related documentation in accordance with correct revisions of drawings, specifications, and procedures, and in accordance with the requirements of customers, Engineering and Development groups and regulatory agencies.

h) scheduling the release of manufacturing orders for parts, subassemblies and assemblies to meet production requirements.

i) implementing changes to Process Sheets, Inventory Data Sheets and related documentation that result from design changes.

j) determining Quality Assurance Program levels for components and materials in co-operation with Quality Assurance.

k) preparing detailed estimates for manufacturing including sub-contract work calling for CSA Quality Assurance Program requirements.

## 9.14 MANAGER, QUALITY ASSURANCE & REGULATORY AFFAIRS

The Manager, Quality Assurance & Regulatory Affairs is responsible for the following:

a) training and development of Quality Assurance, Regulatory Affairs and Quality Control personnel in accordance with established policies and procedures.

b) all inspection, testing and calibration activities.

c) regulatory licensing activities and reporting requirements of regulatory authorities.

d) the administration of the THERATRONICS quality system.

## 9.15 QUALITY ASSURANCE OFFICERS

Quality Assurance Officers (including Senior Quality Assurance Officers and Design Assurance Engineers) are responsible for:

a) formulation, co-ordination and promulgation of policies, procedures and guidelines related to quality for both hardware and software.

b) ensuring that training programs are developed and implemented to assure that all individuals performing activities affecting quality have been trained to achieve and maintain suitable proficiency.

c) monitoring and evaluating the effectiveness of quality related training programs.

d) monitoring product software and hardware conformance with the requirements described in the Quality Assurance Manual, with the authority, responsibility and freedom to identify and evaluate quality problems and to ensure that proper and complete corrective action is taken.

e) establishing internal quality audit plans and schedules, conducting audits and following up on corrective action requirements.

f) ensuring that complaints are properly identified, investigated and resolved.

g) providing guidelines and assistance to Engineering and Development Groups in the preparation of inspection and test plans for hardware and software. Evaluating the completed plans to determine suitability for the purpose intended.

h) maintaining approved suppliers lists and evaluating suppliers with respect to quality, including manual reviews, surveys and external quality audits.

i) preparing or having prepared Manufacturing Inspection and Test Plans and reviewing production and procurement instructions to ensure that contractual requirements with respect to quality are covered.

j) preparing or having prepared History Files/Dockets as required by customer contracts.

k) authorizing the release for shipment of finished products when required by contract to assure that all quality requirements have been met.

l) ensuring compliance with regulatory authority reporting requirements.

## 9.16 QUALITY CONTROL SUPERVISOR

The Quality Control Supervisor reports to the Manager, Quality Assurance & Regulatory Affairs. The Quality Control Supervisor is responsible for:

a) ensuring that hardware and software components, materials, and finished products are inspected in accordance with Quality Assurance Program requirements and in accordance with the schedule priorities required by Manufacturing.

b) ensuring that measuring and testing equipment is calibrated in accordance with Quality Assurance Program requirements.

c) providing direction and training to the Quality Control Inspectors.

d) ensuring that non-destructive testing personnel are qualified and certified to provide non-destructive testing services.

## 9.17 QUALITY CONTROL INSPECTORS

Quality Control Inspectors, are responsible for:

a) inspecting raw materials and other purchased items including review of accompanying documentation.

b) carrying out finished product and in-process inspections, tests and examinations as called for on the Manufacturing Order.

c) authorizing the release of finished components and products into stores, finished goods inventory, material review or to the Technical Review Team as applicable.

d) calibration of measuring and testing equipment to established procedures and schedules and maintenance of calibration records.

e) monitoring of special processes where required by Manufacturing, Inspection and Test Plans in accordance with written checklists.

f) recording and reporting of specified data and information in accordance with procedures established by Quality Assurance.

g) providing non-destructive testing services.

## 9.18 RADIATION SAFETY OFFICER

Radiation Safety Officer is responsible for:

a) administering the Radiation Safety program.

b) obtaining valid regulatory licenses and approvals from all National and International Agencies needed to carry on the business of THERATRONICS.

c) maintaining records of all licensing and regulatory approvals and certificates for THERATRONICS equipment and ensuring that all departments using the certificates are in possession of current copies to avoid Notices of Violations and/or fines from Regulators.

d) keeping abreast of regulatory changes taking place both Nationally and Internationally through publications such as the Canada Gazette, Health Canada Notices, U.S. Federal Register, U.S. Code of Federal Regulations, U.S. Food and Drug Publications and U.S. Nuclear Regulatory Commission. Promptly notifying all affected staff of suggested, pending or newly implemented legislated changes to regulations.

## 9.19 MANAGER, COMPUTER PRODUCTS ENGINEERING & DEVELOPMENT

The Manager, Computer Products Engineering & Development, reporting to the Vice-President Engineering and Development is responsible for the engineering and development of new products and changes to existing products within the Computer Products product line.

## 9.20 MANAGER, COMPUTER PRODUCTS ENGINEERING SUPPORT

The Manager, Computer Products Engineering Support, reporting to the Vice-President Engineering and Development is responsible for the support of the installed base of the Computer Products product line, and for administration of services for Computer Products Engineering.

## 9.21 MANAGER, THERAPY SYSTEMS ENGINEERING & DEVELOPMENT

The Manager, Therapy Systems Engineering & Development, reporting to the Vice-President Engineering and Development is responsible for the engineering and development of new products and changes to existing products within the Therapy Systems product line.

## 9.22 MANAGER, THERAPY SYSTEMS ENGINEERING SUPPORT

The Manager, Therapy Systems Engineering Support, reporting to the Vice-President Engineering and Development is responsible for the support of the installed base of the Therapy Systems product line, and for administration of services for Therapy Systems Engineering.

## 9.23 GENERAL MANAGER, SERVICE & TECHNICAL SUPPORT

The General Manager, Service & Technical Support shall:

a) define the responsibilities and authority of all service managers.

b) ensure that the required training, equipment and documentation are made available such that all installation, service and technical support work can be carried out in accordance with Quality Assurance, Engineering and Sales specifications and done so in accordance with established policies and procedures.

c) establishes new Service and Technical Support policies and procedures.

d) define the responsibilities and authority of technical support personnel.

e) ensure that technical support information is provided in a correct and timely fashion to service representatives, agents, distributors and customers.

f) handles administration and management of central dispatch functions.

g) technical training of Company personnel, agents, distributors and customers.

## 9.24 MANAGER, INSTALLATION AND SERVICE

The Manager, Installation and Service shall:

a) define the responsibilities and authority of installation and service personnel.

b) co-ordination of all equipment installations world-wide.

c) ensuring that all products are installed and commissioned in a manner such that they meet Quality Assurance, Engineering, and Sales specifications and the requirements of the Regulatory Authorities.

d) ensures that all service work carried out on equipment is done so in accordance with established policies and procedures.

e) ensures that all installation personnel clearly explain and demonstrate the equipment to the satisfaction of the customer.

f) training and development of installation personnel and directing their activities in accordance with established policies, procedures and guidelines.

## 10. VERIFICATION OF QUALITY BY CUSTOMERS

Where specified in the contract, the customer Quality Assurance Representative (QAR) may perform a product inspection or Quality System audit at THERATRONICS. In such a case the QAR shall be provided with the facilities required for the proper accomplishment of his work. THERATRONICS shall also supply the QAR with any assistance requested for verification, documentation, or release of product.

The customer may also perform a product inspection upon receipt and installation at his premises to establish that the product conforms to contract and specification requirements. Verification by the customer does not absolve THERATRONICS of the responsibility to provide acceptable product nor shall it preclude subsequent rejection.

The QAR's rights as specified in this section are extended to THERATRONICS' subcontractors. That is, where specified by the contract, the QAR may have access to a subcontractors' facilities in the performance of his work.

When the QAR performs verification at a THERATRONICS subcontractor facility, such verification shall not be used by THERATRONICS as evidence of effective control of quality by that subcontractor.

Where specified by the contract, the QAR shall have the right to verify any process, procedure or inspection to determine compliance with the contract.

Measuring and testing equipment shall be made available for use by the QAR for verification. THERATRONICS personnel shall be provided to operate these tools, if required.

## 11. ELEMENTS OF THE QUALITY SYSTEM

### 11.1 MANUFACTURING, INSPECTION AND TEST PLAN (CSA CONTRACTS ONLY)

THERATRONICS shall establish and maintain procedures indicating the requirements for inspection, test and verification of items and services for all phases of a manufacturing contract.

Quality Assurance is responsible for preparing and approving all Manufacturing Inspection and Test Plans. The requirements for Manufacturing, Inspection and Test Plans are detailed in 5.00-QA-01.

Quality Assurance is also responsible for:

a) incorporating into the MITP the inspection and test points in sequence with the production operations including incoming inspection, preservation, packing and when applicable, site inspections and testing.

b) submitting MITP to the customer for acceptance, where required by contract.

c) approving all inspection and test procedures, and the submission of the appropriate procedures with the MITP, on request when specified in the contract.

d) updating the MITP when inspection and/or test procedures are revised, and resubmit to the customer for acceptance.

e) ensuring that revisions to MITP's and procedures receive the same authorizing signatures as the original document.

Production Engineering is responsible for reviewing all Manufacturing Inspection and Test Plans in conjunction with Quality Assurance.

The Production Planning Staff is responsible for producing the necessary planning details.

Production Planning Staff ensure that Quality Assurance receive the production planning processes for information in preparing the Manufacturing, Inspection and Test Plans.

The Production Planning Staff is also responsible for ensuring customer and jurisdictional hold, witness and verification points are identified on the applicable production documents.

## 11.2 QUALITY PROGRAM LEVELS

THERATRONICS shall establish the responsibilities and methods for evaluating the need for, and for selecting appropriate quality program levels to be assigned to suppliers for the procurement of items or services.

Quality Assurance in conjunction with the Production Planning Staff shall evaluate, document and approve the quality program levels assigned to suppliers. The procedure for determination of quality program levels is outlined in 5.00-QA-02.

Specifying a Quality Program Level does not absolve the supplier of the responsibility to supply an item or service to the specified requirements.

## 11.3 TENDER AND CONTRACT REVIEW

THERATRONICS shall establish and maintain procedures for reviewing tender and contract requirements.

All tender and contracts shall be reviewed to ensure:

a) the requirements are adequately defined and documented;

b) any requirements differing from those in the tender and contract are resolved; and

c) the Company's capability to meet the tender and contract requirements.

The review of tenders and contracts shall be administered by Sales, Contracts and Business and Manufacturing.

Amendments to tenders and contracts are reviewed, accepted and implemented at the same level as the original. These requirements are implemented according to 5.00-QA-03.

Records of tenders and contracts shall be maintained according to 5.00-QA-18.

## 11.4 DESIGN CONTROL

THERATRONICS shall establish and maintain procedures for the control and verification of design activities in order to ensure that the specified requirements are met. The details of such control and verification is documented in 5.00-QA-04.

The Engineering Manager shall prepare a project plan for each design and development activity (other than minor design changes).

The project plan shall describe the activities involved and define responsibility for their implementation.

Engineering Management shall ensure that the task of performing design activities is assigned to qualified personnel. Resources shall be identified in the project plan.

The project plan shall be updated as the design evolves.

In the case of multiple development groups, the project plan shall identify the organizational and technical interfaces between different groups.

Design input shall take into consideration the results of any contract review activities.

Problems encountered during the design activities shall be resolved and documented.

At appropriate stages in the design, formal design reviews shall be performed. These reviews shall be identified in the project plan. Participants at design reviews include representatives of all departments concerned with the design stage being reviewed and may include others, as required. Records of reviews shall be documented.

Validation activities shall meet the requirements of Design Validation SOP #3.24-AA-11.

Verification of Validation shall be performed by peer review of the validation protocol, and by review of the test results to ensure that expected results were achieved.

Verification of detailed design documents shall be performed by peer review.

Changes to final, approved designs shall be subject to the same design controls as were applied to the original design. Design activity which consists of minor changes to existing design may be conducted and validated according to procedure 3.24-AA-01.

## 11.5 DOCUMENT & DATA CONTROL

THERATRONICS shall establish and maintain procedures for controlling and maintaining all essential documents and data affecting products, and to identify the responsibilities for preparation, review, revision, approval and distribution of these documents.

Department Managers shall establish and maintain the document and data control system applicable to their area in accordance with 5.00-QA-05.

All documents and data are reviewed for adequacy and approved by authorized personnel before issue.

Department Managers shall establish an index of all essential documents identifying the current revision of documents to preclude use of non-current documents.

Department Managers shall ensure:

a) appropriate documents are available at all locations where operations are performed which impact the quality system.

b) obsolete documentation is promptly removed from all points of issue.

c) documents and data retained for legal and/or knowledge-preservation will be clearly identified as being obsolete.

d) revisions to documents and data shall be reviewed and approved by the same level of approval authority as the original.

e) document and data revisions shall be identified in the document, if practical.

Department Managers shall have access to pertinent background information upon which to base their review and approval.

## 11.6 MEASURING AND TEST EQUIPMENT

THERATRONICS shall establish and maintain procedures to control, calibrate and maintain inspection, measuring and test equipment, including test software, which is used to demonstrate conformance of product to requirements. The procedures are 5.00-QA-06 and supporting Gauge Calibration Procedures.

All users of Measuring and Test Equipment (MTE) are responsible to assure that the MTE is used in a manner which ensures that the measurement capability, accuracy, precision, stability and range is known and consistent with the intended application.

Where jigs, fixtures, templates or patterns are used for inspection purposes (ie. to determine compliance with specifications), they shall be checked by Quality Control to verify their capability to accept items to meet specified requirements prior to their release to manufacturing. These items shall be rechecked on a periodic basis. Procedure and frequency of these checks shall be defined in Gauge Calibration Procedures.

Where computers are used as part of an automated quality control system, the computer software programs shall be validated by adequate and documented testing. Program changes shall receive the same level of approval authority as the original. Validation and test records shall be maintained by Quality Control.

Where a customer or regulatory authority requires technical data pertaining to THERATRONICS measurement and test equipment to establish that the equipment is functionally adequate, Quality Assurance shall make such data available.

All personnel using measurement and test equipment are responsible for selecting appropriate equipment and methods which are capable of providing the required accuracy and precision.

All MTE shall be calibrated and adjusted prior to use and at prescribed intervals, against standards traceable to certified national standards. Intervals for each class of MTE are defined in 5.00-QA-06. Quality Control is responsible for the administration of the calibration system.

All MTE shall be calibrated in accordance with 5.00-QA-06 and the appropriate Gauge Calibration Procedure. These procedures details equipment type, unique identification, location, frequency of checks, check method, acceptance criteria and action to be taken when results are unsatisfactory.

Quality Control shall identify all MTE with a label indicating calibration due date and identification of individual who performed the last calibration.

Quality Control shall maintain all calibration records.

When MTE is found to be out of calibration, an investigation shall be carried out by Quality Assurance to determine the potential impact to previously inspected items.

Quality Control shall assure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

Users of MTE are responsible for ensuring that handling, preservation and storage of MTE is suitable to maintain accuracy and fitness for use.

Where an adjustment to MTE would invalidate the calibration, a tamper-proof label is applied by Quality Control after the calibration to prevent such adjustment and maintain the calibration status.

## 11.7 PROCUREMENT

THERATRONICS shall establish and maintain a system for controlling purchased items and services and ensuring conformance to specified requirements. This applies to the procurement of all items and services purchased for both THERATRONICS Products and Contract Manufacturing Products. The procedure for procurement control is described in 5.00-QA-07.

Materials Controls shall ensure that all items and services procured shall be purchased from suppliers who have the ability to supply quality items and services that meet or exceed the required specifications including the quality requirements.

The type and extent of control exercised over suppliers shall be dependent on:

a) type of product or service

b) impact of the product or service on the quality of the final product and, where applicable:

c) on quality audit reports or supplier checklists;

d) on quality records of previously demonstrated capability and performance of the supplier

This control is described in procedure 5.00-QA-07 and is also described in further detail in the Supplier Qualification Program, SOP 3.13-AA-01.

Procurement records shall be retained in accordance with 5.00-QA-18 and 5.00-QA-05.

Procurement activities are initiated by authorized personnel (reference 3.11-MC-08) who shall include:

a) a clear description of the type, class, grade, title, number, etc., including applicable issues or revisions of specifications, drawings, Inspection and Test Plan requirement and other relevant technical data.

b) requirements for approval or qualification of documentation, items or services, procedures, processes, equipment and personnel.

c) title, number and issue of the Quality Assurance Program Standard to be applied to the item or service.

Review and approval of purchasing documents (CSA Items) lies with the Quality Assurance Department.

## 11.8 INTERNAL QUALITY AUDITS

THERATRONICS shall establish maintain procedures for planning and implementing quality audits to evaluate and verify the effectiveness of the quality programs, compliance with the quality program standards and regulatory requirements. The procedure for performing audits is defined in 5.00-QA-08.

Quality Assurance shall establish the frequency of the audits based on the status and importance of the activity to be audited.

Audits shall be performed by personnel who are independent of the activity being audited.

The Auditor shall record the results of the audit and meet with the Department Manager to discuss the results.

Any corrective actions shall be brought to the attention of the Departmental Manager.

Departmental Managers shall ensure timely resolution of any corrective actions as specified in 5.00-QA-20.

The Auditor shall follow up by reviewing the corrective actions taken and verify they have been fully completed.

## 11.9 INSPECTION & TEST STATUS

THERATRONICS shall establish and maintain procedures to provide positive evidence that required inspections and tests are performed indicating conformance or nonconformance of the item.

Quality Control shall indicate the conformance or nonconformance of items by the application of stamps, tags, manufacturing orders or other suitable means as defined in 5.00-QA-09.

## 11.10 INCOMING INSPECTION

THERATRONICS shall establish and maintain procedures to identify, inspect, store and control items and services to ensure conformance to specified requirements, and prevent mix-ups and use of incorrect or defective items and services.

Receiving is responsible for identifying all goods delivered and forwarding to Incoming Inspection.

Incoming Inspection is responsible for inspecting all items purchased to a THERATRONICS drawing and/or specification.

Incoming Inspection inspects the item in accordance with the requirements of the Purchase Order, Inspection and Test Plan and 5.00-QA-10.

## 11.11 IN-PROCESS INSPECTION

THERATRONICS shall establish and maintain procedures for controlling the inspections and tests performed on items during the production phase in accordance with specified requirements and the requirements in 5.00-QA-11.

Quality Control is responsible for in-process inspection.

Quality Control inspects items and services in accordance with the requirements of the manufacturing order.

Quality Control identifies any nonconformance, segregates and prepares the necessary reports. Nonconforming items are processed as per 5.00-QA-19.

After completion of each operation, the Quality Control Inspector shall indicate the accept/reject status.

## 11.12 FINAL INSPECTION/FINISHED DEVICE INSPECTION

THERATRONICS shall establish and maintain procedures to conduct and document final inspection/finished device inspection and the activities to ensure conformance of the finished product to the specified requirements.

Quality Control performs inspections on each item, lot or batch of items upon completion of the last specified production operation on the Manufacturing Order, to ensure all

specified inspections and tests are completed and meet specified requirements. Specific requirements are detailed in 5.00-QA-12.

All final inspection/finished device inspection records and associated data shall be retained and maintained as Quality Records in accordance with 5.00-QA-18.

## 11.13 IDENTIFICATION AND TRACEABILITY

THERATRONICS shall establish and maintain procedures for identification of items or services and when contractually, jurisdictionally or regulatory authority required, establish a unique identifier for the purpose of maintaining traceability of lots, batches or individual items.

Product Engineering shall be responsible to establish the need for, and location of the item identification and/or serialization including the method of application in accordance with 5.00-QA-13.

## 11.14 PRODUCTION

THERATRONICS shall establish and maintain procedures to define the responsibilities, procedures and method used in the production cycle.

The Plant Manager, Plant and Process Engineer, Production Planning and Control Manager and Materials Control Manager maintain a Manufacturing Control Procedures Manual. This manual shall cover all major operations within these groups.

Production activities shall be planned and documented to ensure that the methods used are consistent with good manufacturing practices and meet contractual and specification requirements.

Production Planning activities are defined and documented according to 5.00-QA-15.

## 11.15 SPECIAL PROCESSES

a) THERATRONICS shall establish and maintain procedures to ensure that special processes affecting the quality of items and services, are documented, approved, controlled and performed by qualified personnel.

b) Special processes shall be carried out under controlled conditions, and performed by qualified personnel using approved written procedures and qualified equipment, where required by the applicable codes, standards, specifications and contract requirements.

c) Manufacturing are responsible for ensuring special process procedures are documented and approved.

d) Special processes carried out at THERATRONICS are detailed in 5.00-QA-16.

## 11.16 HANDLING, STORAGE, PRESERVATION, PACKAGING, DELIVERY AND INSTALLATION

THERATRONICS shall establish and maintain procedures for handling, storage, preservation, packaging, delivery and installation of Company products. These procedures are detailed in 5.00-QA-14 and 5.00-QA-17.

Each production and inspection department shall be responsible for ensuring that safety precautions and good shop practices are maintained to prevent damage or deterioration to the product.

The Plant Manager shall be responsible for training of all operators and the regular maintenance of all moving and lifting equipment.

Designated storage areas shall have adequate space for orderly placement and identification of items to prevent damage or deterioration of product.

Storage areas shall have access limited to authorized personnel only.

Receipt of acceptable items into storage and the issuing of items out of storage requires authorized documentation. Detailed documentation requirements are described in 5.00-QA-10, 5.00-QA-12 and Manufacturing Control Procedures, 3.11 series.

Product Engineering shall ensure the packaging is structurally designed to adequately protect the product from deterioration during handling, storage and shipment of the product.

Manufacturing shall ensure specified preserving and packing procedures are followed in accordance with engineering drawings, the Manufacturing Order, Packing Lists and 5.00-QA-17. The Device Master Record shall contain packaging specifications, including methods and procedures used.

After final inspection and testing has been performed, Manufacturing shall package all products for shipping and hold for authorization to ship. The Plant Manager is responsible to assure that this requirement is met.

Quality Control/Quality Assurance shall authorize shipment of the product.

Protection of the products shall be extended to include delivery to destination and installation where specified in the contract.

Quality Control shall conduct quarterly inspections of handling and storage activities to assure product condition and shelf-life control.

## 11.17 QUALITY RECORDS

THERATRONICS shall establish and maintain procedures for identification, collection, indexing, access, filing, storage and maintenance of quality records. Quality Records shall be maintained according to 5.00-QA-18.

Quality Records shall be maintained as objective evidence of the effective operation of the quality system and to demonstrate conformance to specified requirements.

Quality Records from suppliers shall be maintained in accordance with 5.00-QA-18.

Department Managers shall ensure Quality Records are readily retrievable and provide protection to prevent damage, deterioration or loss.

Quality Assurance shall ensure record retention time periods are compatible with regulatory, jurisdictional and contract requirements according to 5.00-QA-18.

Quality Records shall be made available for evaluation to customers or regulatory agencies.

NOTE: The US FDA and Health Canada do not have access to audit records. FDA and Health Canada auditors may however be granted access to audit procedures and blank audit checklists.

## 11.18 NONCONFORMANCE

THERATRONICS shall establish and maintain procedures to ensure that nonconforming items and services are prevented from unauthorized use or mixing with conforming items. This system includes provisions for the identification of causes for nonconformance and prevention of their recurrence.

Operators and supervisors shall ensure that no item is be released from a work centre until satisfied that all specified requirements have been complied with or nonconformances have been reported in accordance with procedure 5.00-QA-19.

Production Planning/Materials Control are responsible for review of nonconformances and recommend action disposition.

The Plant and Process Engineer shall review and approve dispositions.

Quality Assurance is responsible for final approval of dispositions.

Processing of a nonconforming item or service shall be performed in accordance with procedure 5.00-QA-19.

Quality Control shall inspect the repaired and/or reworked item or service in accordance with the Manufacturing Order requirements.

## 11.19 CORRECTIVE AND PREVENTIVE ACTION

THERATRONICS shall establish and maintain procedures for implementing corrective/preventive action. The corrective/preventive action process is maintained in accordance with 5.00-QA-20.

All corrective/preventive actions taken shall deal with problems to a level corresponding to risks encountered.

Implementing and recording changes in procedures resulting from corrective/preventive action shall be administered according to 5.00-QA-20.

Customer complaints are administered in accordance with 5.00-QA-24 which meets the requirements of FDA, USNRC, AECB and Health Canada regulations.

Corrective/Preventive action procedures include instructions for the investigation of the adverse condition to determine the root cause; to determine corrective/preventive action required to prevent recurrence; and for recording the results of the investigation.

Quality Assurance shall oversee the administration of the corrective/preventive action system.

Quality Assurance shall establish controls to ensure that corrective/preventive action is taken and that it is effective.

Documents which may be reviewed for conditions affecting quality and possible corrective/preventive action are outlined in 5.00-QA-20.

Quality Assurance shall ensure corrective/preventive action status is reviewed by management as required.

## 11.20 CUSTOMER SUPPLIED PRODUCTS OR SERVICES

THERATRONICS shall establish and maintain procedures for verification, storage and maintenance of customer supplied products and services which are provided for incorporation into an item, service or related activity. Customer supplied products and services are controlled according to 5.00-QA-21.

Quality Control/Quality Assurance shall be notified when damage or malfunction occurs during storage, assembly or testing. Quality Control/Quality Assurance shall then notify the customer of the nonconformance according to the procedure specified in the customer contract.

Nonconformance of customer supplied products does not absolve the customer of the responsibility to provide acceptable products.

## 11.21 STATISTICAL TECHNIQUES

THERATRONICS shall establish and maintain procedures describing the sampling plan used for inspection and testing purposes. The sampling plan is described in 5.00-QA-22.

Statistical sampling inspection techniques may be used for incoming, in-process and final inspections.

## 11.22 TRAINING

THERATRONICS shall establish and maintain procedures identifying training needs and provide for the training of personnel performing activities relating to the quality of products and services supplied. The procedure for training is described in 5.00-QA-23.

Department Managers shall ensure new personnel hired for positions relating to the quality of products and services have the prerequisite levels of education, training and qualification.

Human Resources shall ensure individual training records are retained and maintained in their employee training record file.

## 11.23 HANDLING OF COMPLAINTS

THERATRONICS shall establish and maintain procedures to specify the responsibilities, requirements and methods for receiving, recording, classifying, investigating, analysing, reporting and resolving all complaints by the Company.

Quality Assurance & Regulatory Affairs shall oversee all steps in the handling of Complaints and provide appropriate instructions and training to company employees.

Company employees shall report complaints to Quality Assurance. The definition of a Complaint is detailed in 5.00-QA-24.

Quality Assurance & Regulatory Affairs shall handle all complaints according to 5.00-QA-24.

## 11.24 LABELLING

THERATRONICS shall establish and maintain procedures to define the responsibility, methods and controls required to maintain the integrity of labelling of finished, devices, accessories and spares. This shall be performed in accordance with 5.00-QA-25. SOP #5.00-QA-25 meets the requirements of US FDA 21 CFR Part 820 - Medical Devices GMP.

The Manager of the Product Engineering Group shall ensure that labelling and labels are designed, documented and adequately provide instructions as to purpose, conditions, operations, safety and maintainability as determined by the product/software specifications of a device.

It shall be the responsibility of the Product Engineering Group Manager to ensure that labelling and labels are documented by drawing and/or procedures.

The Manager of the Product Engineering Group shall ensure that inspection procedures for verification of labelling requirements are documented.

Quality Control shall ensure labelling and labels are correct to drawings and/or procedures.

Quality Control shall ensure the labelling and labels are applied to the device, accessory or spare parts in accordance with the specified requirements.

## 11.25 QUALITY PLANNING

THERATRONICS shall define the process of identifying the quality system practices and sequence of activities relevant to providing quality products and services.

The responsibility and authority for quality planning during the different phases of a project are reflected in 5.00-QA-04, 5.00-QA-07, 5.00-QA-10, 5.00-QA-11, 5.00-QA-12, 5.00-QA-15 and 5.00-QA-17.

A quality plan shall be prepared by Quality Assurance for new or redesigned products. The identification for need of an individual Quality Plan is described in 5.00-QA-04.

Quality plans for existing product lines are described in 5.00-QA-26.